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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,087	10/28/2003	Asahi Sakai	2003-1531	3481

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EXAMINER

CORRIGAN, JAIME W

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/694,087	Applicant(s) SAKAI, ASAHI	
	Examiner Jaime W. Corrigan	Art Unit 3748	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10-28-03</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorsuch (PN 5,980,481).

Regarding claim 1 Gorsuch discloses a recirculation (See Abstract) method of dialysate which comprises continuous flow of dialysate out of (See Figure 1, Abstract, Column 1 Lines 63- 67, Column 2 Lines 1-18) peritoneal cavity, recirculation through a closed line (See Figure 1), filtering out of a portion of the dialysate through a semipermeable membrane on the way (See Figures 1, 2 (14), (32), (33), (34), (38), Column 3 Lines 39-45), supplementing a comparable volume of fresh dialysate (See Figures 1, 2 (12), (26), (31), (32), (34), (38), Column 3 Lines 39-45), through a semipermeable membrane having a maximum permeable molecule of up to 5,000 dalton (See Column 4 Lines 66-67, Column 5 Lines 1-64) , and returning into (See Figure 1, Abstract) peritoneal cavity.

Regarding claim 4 Gorsuch discloses osmotic agents selected from glucose (See Column 4 Lines 50-52), amino acids (See Table 1, Columns 9-10), fatty acids, and peptides is added to the recirculation line.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-3 rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsuch (PN 5,980,481) in view of Milner (PN 4,886,789).

Gorsuch discloses the invention as recited in claim 1 above and further discloses polymer osmotic agents is plasma protein or oligosaccharide (See Column 8 Lines 1-4).

Gorsuch fails to disclose polymer osmotic agents is added to the recirculation line.

Milner teaches that it is conventional in the art to utilize polymer osmotic agents is added to the recirculation line (See Column 15 Lines 16-21).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized polymer osmotic agent taught by Milner in the Gorsuch device since it would improve dialysate flow control.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsuch (PN 5,980,481) in view of Valentine et al. (PN 5,037,419).

Gorsuch discloses the invention as recited in claim 1 above, however, fails to disclose reductants or anti-oxidants are glutathione, vitamin C or vitamin E and are added to supplementing fluid.

Valentine et al. teaches that it is conventional in the art to utilize reductants or anti-oxidants are glutathione, vitamin C or vitamin E and are added to supplementing fluid (See Column 1 67-68, Column 2 Lines 1-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Gorsuch to include the reductants or anti-oxidants, which are added to supplementing fluid as taught by Valentine since it would improve dialysate reduction and anti-oxidation.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gorsuch (PN 5,980,481) in view of Izaka et al. (PN 3,876,775).

Gorsuch discloses the invention as recited in claim 1 above, however, fails to disclose stabilizers preventing the recycled protein denatured is added to supplementing fluid.

Izaka et al. teaches that it is conventional in the art to utilize stabilizers preventing (See Column 5 Lines 63-66, Column 6 Lines 1-2) the recycled protein denatured is added to supplementing fluid.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Gorsuch to include stabilizers preventing (See Column 5 Lines 63-66, Column 6 Lines 1-2) the recycled protein denatured is added to supplementing fluid taught by Izaka et al. since it would improve electrophoretic analysis.

### ***Allowable Subject Matter***

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Roberts et al. (PN 5,944,684) and Ash (PN 5,906,978) disclose similar peritoneal dialyzing fluid systems.

Any inquiry concerning this communication from the Examiner should be directed to Examiner Jaime Corrigan whose telephone number is (571) 272-4858. The Examiner can normally be reached on Monday – Friday from 8:30 a.m. – 6:00 p.m. 2<sup>nd</sup> Friday off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kevin C. Sirmons, can be reached on (571) 272-4965. The fax number for this group is (571) 273-8300.

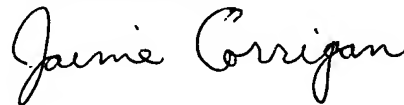
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-3700.

JC

April 30, 2006

Jaime Corrigan



Patent Examiner  
Art Unit 3767

KEVIN SIRMONS  
PRIMARY EXAMINER

